

## CLAIMS

The invention is claimed as follows:

1. A system for detecting leaks in a dialyzer, the dialyzer including a bundle of hollow fibers with walls having pores, the system comprising:
  - 5 a device for injecting variously sized physiologically safe particles into a lumen of each of at least a majority of the fibers, wherein at least a majority of the particles are too large to pass through a majority of the pores of the walls; and
  - a particle counter that counts particles that escape through the fiber walls.
- 10 2. The system of Claim 1, which includes a pressurized fluid, wherein the device combines the variously sized particles with the fluid.
3. The system of Claim 1, wherein the pressurized fluid includes pressurized air.
- 15 4. The system of Claim 1, wherein the particles are NaCl.
5. The system of Claim 1, which includes a liquid initially entraining the particles.
- 20 6. The system of Claim 1, wherein the device includes an atomizer.
7. The system of Claim 1, which includes at least one device for removing vapor from the particles before the particles enter the dialyzer.
- 25 8. The system of Claim 7, wherein the moisture removing device is selected from the group consisting of: a heater and a chemical drying device.
9. The system of Claim 1, which includes a device for neutralizing electrically the particles before the particles enter the dialyzer.

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10. The system of Claim 1, which includes a mixing chamber that mixes the particles and the fluid before the particles enter the dialyzer.
11. The system of Claim 10, which includes a plurality of dialyzers in  
5 communication with the mixing chamber.
12. The system of Claim 1, wherein the counter communicates with a plurality of dialyzers.
- 10 13. The system of Claim 1, which includes a plurality of particle counters in communication with the plurality of dialyzers.
14. The system of Claim 1, which includes a flow splitter that splits the flow of particles and fluid before the particles enter the dialyzer.
- 15 15. The system of Claim 14, wherein the counter is a first counter and is in communication with a first path of the split flow, and which includes a second counter that in is communication with a second path of the split flow, the second path not connected to the dialyzer.
- 20 16. The system of Claim 15, which includes a microprocessor that inputs an amount of particles counted by the first and second counters.
17. The system of Claim 1, which includes a plurality of the devices operating in  
25 parallel.
18. The system of Claim 1, which includes a diffuser operable with the dialyzer that disperses the particles so that the particles enter the hollow fibers more evenly.
- 30 19. The system of Claim 1, wherein the particles are introduced into the hollow fibers at a plurality of locations on the dialyzer.

20. The system of Claim 1, which includes a plurality of flow lines extending from the dialyzer to the particle counter.

21. The system of Claim 1, which includes a sequence in which flow of the fluid  
5 and particles is switched from a first flow path through the dialyzer to a second flow path through the dialyzer, wherein particles flowing through the first and second paths are counted.

22. A system for detecting leaks in a dialyzer including a bundle of hollow fibers  
10 having porous walls, the system comprising:  
a solution including physiologically safe particles;  
a device that creates an aerosol from the solution; and  
wherein the aerosol is injected inside the hollow fibers and a particle counter counts particles flowing through at least one of the fiber walls.

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23. The system of Claim 22, wherein the solution includes from about .001 to about 99% percent salt in water.

24. The system of Claim 22, wherein the particles are about thirty nanometers to  
20 about two microns in size.

25. The system of Claim 22, which includes a heater that blows heated air into a mixing chamber with the aerosol.

25 26. The system of Claim 22, wherein the hollow fibers have inner surfaces defining pore openings of about five nanometers to about one hundred nanometers.

27. The system of Claim 22, wherein the particle counter is a condensation nucleus counter.

28. The system of Claim 22, wherein at least one of a plurality of blood receiving/discharging ends of the dialyzer serves as an inlet for the aerosol and at least one of a plurality of dialysate ports serves as an outlet for at least vapor of the aerosol to escape from the hollow fibers.

29. The system of Claim 28, which includes a plurality of flow control devices in communication with the blood ends and the dialysate ports, the flow control devices providing a plurality of selectable flow paths through the dialyzer.

30. A method of testing a dialyzer for leaks comprising the steps of:  
(a) creating an aerosol having physiologically safe polydisperse particles;  
(b) forcing the aerosol into hollow fiber walls bundled in the dialyzer; and  
(c) rejecting the dialyzer if at least a threshold amount of particles escape through the fiber walls.

31. The method of Claim 30, which includes the step of pressurizing the aerosol.

32. The method of Claim 30, which includes the step of drying the aerosol.

33. The method of Claim 32, wherein drying the aerosol includes mixing the aerosol with heated air.

34. The method of Claim 30, which includes the step of removing static electrical charge from the aerosol.

35. The method of Claim 30, which includes the step of adjusting the pressurization of the aerosol to adjust a time needed to determine if the threshold amount has been reached.

36. The method of Claim 30, which includes the step of adjusting at least one of a concentration of particles formed in the aerosol and a pressure of the aerosol to adjust for a number of dialyzers connected operably to the pressurized aerosol.
- 5 37. The method of Claim 30, which includes creating multiple aerosol streams to adjust for a number of dialyzers connected operably to the pressurized aerosol.
38. The method of Claim 30, which includes the step of condensing alcohol onto particles that have passed through the fiber walls and counting the condensated  
10 particles to determine if the threshold amount has been reached.
39. The method of Claim 30, which includes the step of splitting the pressurized aerosol into multiple flow paths and determining if the testing is functioning properly by counting particles in one of the split paths.
- 15 40. The method of Claim 30, wherein the threshold amount of particles is based on a number of particles that pass through the fiber walls of a non-leaking dialyzer.
41. A method of testing a dialyzer for leaks comprising the steps of:  
20 (a) varying a concentration of a particle producing matter in a liquid to vary sizes of particles produced when entraining the matter and liquid in a gas stream;  
(b) removing the liquid from the gas stream;  
(c) flowing the gas and particles into hollow fibers bundled in the dialyzer;  
and  
25 (d) counting particles that escape from the fibers.
42. The method of Claim 41, wherein increasing the concentration increases the size of the particles.
- 30 43. The method of Claim 41, wherein a given concentration yields multiple sizes of particles.

44. The method of Claim 41, which includes the step of selecting the concentration to produce particles of a size that operates suitably with a pore size of pores defined by the hollow fibers.

5 45. The method of Claim 41, wherein the matter is sodium chloride, the liquid is water and the gas is air.

46. A method of testing leaks in a dialyzer having a housing, the housing having first and second potted ends, first and second dialysate ports, the first port located near  
10 the first end and the second port located near the second end, a bundle of hollow, porous fibers having fiber walls placed inside the housing fibers so that ends of the fibers extend through the potted ends, and wherein blood flows within the fiber walls and dialysate flows inside the housing and outside the fiber walls, the method including the steps of:

15 at the first end, flowing particles entrained in a gas to pass within the fiber walls and flowing at least the gas across the fiber walls and out the first port to test the fibers near the first end of the housing; and

at the second end, flowing particles and gas within the fiber walls and flowing at least the gas across the fiber walls and out the second port to test the fibers near the  
20 second end of the housing.

47. The method of Claim 46, which includes the step of flowing at the first end particles and gas within the fiber walls and flowing at least the gas across fiber walls and out the second port to test the fibers near the middle of the housing.  
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48. The method of Claim 46, which includes the step of flowing particles and gas within the fiber walls at both the first and second ends of the housing and flowing at least the gas across fiber walls and out the second port.

30 49. The method of Claim 46, which includes the step of flowing particles and gas within the fibers at both the first and second ends of the housing and flowing at least the gas across fiber walls and out the first and second ports.

50. A method of testing for leaks in a dialyzer comprising the steps of:
- (a) varying a concentration of a particle producing matter in a liquid to vary sizes of particles produced when entraining the matter and liquid in a gas stream;
  - 5 (b) flowing the gas and particles into hollow fibers bundled in the dialyzer;
  - (c) adding to a size the of particles; and
  - (d) counting particles that escape from the fibers.
51. The method of Claim 50, which includes the step of drying the particles before
- 10 enlarging the particles.
52. The method of Claim 50, wherein adding to the size of the particles includes condensing a liquid onto the particles.